



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,346	10/10/2003	Keun Ho Chun	58248-CIP2 (47606)	9221
21874	7590	06/29/2006	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			BAUSCH, SARAE L	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 06/29/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/684,346

Applicant(s)

CHUN ET AL.

Examiner

Sarae Bausch

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-228 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-228 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 5-9 and 58-61 drawn to a affinity probe with a probe ligand recognition element, classified in class 536, subclass 23.1.
 - II. Claims 10-26 and 62-65, drawn to cleavage probe with a destabilizing agent, classified in class 536, subclass 24.5.
 - III. Claims 27-33 and 66-69, drawn to type I coupling probe, classified in class 536, subclass 23.4.
 - IV. Claims 34-46 and 70-73, drawn to type II coupling probe, classified in class 424, subclass 178.1.
 - V. Claims 47-57 and 74-77, drawn to type II(-) coupling probe, classified in class 536, subclass 24.3.
 - VI. Claims 79-81, 92-93, 110-11, 122-129, 138-142, 153-156, 163-4, drawn to bimolecular probe, classified in class 536, subclass 24.1.
 - VII. Claims 94-105, 112-116, 143-148, 149-152, 165-166, drawn to unimolecular probe, classified in class 536, subclass 24.2.
 - VIII. Claims 118-121, 136-137, drawn to trimolecular probe, classified in class 536, subclass 24.31.
 - VIII. Claims 167-8, 173, 178-9, 180, 185, 211-212, 217 drawn to assay for detection using an affinity probe, classified in class 435, subclass 6.

Art Unit: 1634

- IX. Claims 169, 174, 178-179, 181, 186, 213, 218, drawn to an assay for detection using a cleavage probe, classified in class 435, subclass 91.3.
- X. Claims 170, 175, 178-179, 182, 185, 214, 219, drawn to an assay for detection using a type I coupling probe, classified in class 435, subclass 91.1.
- XI. Claims 172, 177, 178-179, 184, 188, 215-216, 220-221, drawn to assay for detection using type II coupling probe, classified in class 435, subclass 91.2.
- XII. Claims 189-194, 198, drawn to assay for detection using a bimolecular probe, classified in class 435, subclass 6.
- XIII. Claims 197, 201-210, drawn to assay for detection using a unimolecular probe, classified in class 435, subclass 69.2.
- XIV. Claims 199, drawn to assay for detection using a trimolecular probe, classified in class 435, subclass 91.5.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I-VIII and IX-XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the probes of group I-VIII can be used for protein purification, in situ hybridization, encoding proteins which are not required for the methods of group IX-XIV. Furthermore the search for an assay for detection is not coextensive with a search for a probe.
- 3. The inventions of groups I-VIII are patentably distinct because they are drawn to different products having different structures and functions. The affinity probe of group I is

Art Unit: 1634

composed of recognition element that is a probe ligand. The cleavage probe of group II is composed of a destabilizing agent and a cleavage site. While the type I coupling probe of group III is composed of coupling element that specifically conjugates a destabilizing to a reaction site. The type II coupling probe of group IV is composed of a coupling element that is structurally and functionally different that the type I coupling probe in that it has a reaction inducing agent that specifically converts the reaction site of the conjugation site to the destabilizing agent. The type II(-) coupling probe of group V is composed of a destabilizing agent that is conjugated to a different non-conjugable site. The unimolecular probe of group VI is composed of first object and loop moiety. The bimolecular probe of group VII is composed of and object sequence and a complement sequence. The trimolecular probe of group VIII is composed of third molecule with a second complement sequence. The products of groups I-VIII can be used in materially different processes, for example the probe of group I can be used in hybridization assays, the cleavage probe of group II can be used in a ribozyme assay, the coupling probe of group III can be used in an immunoassay, the coupling probe of group IV can be used to make a nucleic acid array, the coupling probe of group V can be used to make a protein array, the coupling probe of group VI can be used to make a protein fusion molecular, the unimolecular probe of group I can be used in PCR amplification, the bimolecular probe of group II can be used for gene expression, the trimolecular probe of group VIII can be used in a sandwich hybridization assay. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I-VIII are patentably distinct from each other.

Art Unit: 1634

4. The inventions of group IX-XIV are patentable distinct because they are drawn to different methods with different purposes requiring different reagents, reaction conditions, and reaction parameters. The method of group IX does not require the method steps of group X-XIV and vice versa. Additionally, searching the inventions of group IX and group X-XIV would not be used to determine the patentability of the method of group and vice versa.

5. If applicant elects group I a further species election is required. This application contains claims directed to the following patentably distinct species: probe ligand. The species are independent or distinct because each element is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5-8 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. If applicant elects group II a further species election is required. This application contains claims directed to the following patentably distinct species: protease, endonuclease,

Art Unit: 1634

lipase, or glycosidase. If applicant elects protease, applicant must further elect a specific protease. The species are independent or distinct because each element is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 10-11 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. If applicant elects group III a further species election is required. This application contains claims directed to the following patentably distinct species: ligase. The species are independent or distinct because each element is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27-28 are generic.

Art Unit: 1634

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. If applicant elects group IV, a further species election is required. This application contains claims directed to the following patentably distinct species for claims to the cleavage probe: transferase and kinase. Applicant is further required to pick a specific transferase or kinase. The species are independent or distinct because each element is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 34-35 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

Art Unit: 1634

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. If applicant elects group V, a further species election is required. This application contains claims directed to the following patentably distinct species for claims to the cleavage probe: a specific phosphatase. The species are independent or distinct because each element is structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 34-35 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. If applicant elects group XII-XIV, a further species election is required. This application contains claims directed to the following patentably distinct species for claims to the cleavage probe: a specific probe (affinity, cleavage, etc). The species are independent or distinct because each element is structurally and functionally distinct.

Art Unit: 1634

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 189 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

11. Claims 1-4, 82-91, 106-108, 117, 131-135, 157-162, 211-228 link(s) inventions of group I-VIII The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-4, 82-91, 106-108, 117, 131-135, 157-162. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

Art Unit: 1634

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

12. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

13. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

14. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Art Unit: 1634

16. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 10am-7pm.

Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

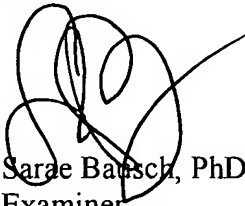
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER



Sarae Baisch, PhD.
Examiner
Art Unit 1634